federal register

WEDNESDAY, OCTOBER 10, 1973

WASHINGTON, D.C.

Volume 38 ■ Number 195

PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

CABINET X-RAY SYSTEMS

Proposed Performance Standard

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 278]

CABINET X-RAY SYSTEMS

Proposed Performance Standard

Pursuant to the authority of the Public Health Service Act as amended by the Radiation Control for Health and Safety Act of 1968 (Public Law 90-602, 42 U.S.C. 263b et seq.), the Commissioner of Food and Drugs proposes to amend Subpart C of Part 278 by adding a new § 278.214 (21 CFR 278.214), prescribing a performance standard for cabinet x-ray systems. The proposed radiation protection standard would apply to cabinet x-ray systems intended for the radiographic and/or fluoroscopic examination or irradiation of objects other than the living human body, and in which the x-ray source, useful beam, and material to be exposed are within an enclosure provided as part of the system.

Cabinet x-ray systems are used for macroscopic inspection of a large variety of materials and objects by industrial manufacturing facilities, laboratories, medical centers, museums, and transportation facilities. Electronic components, castings, welds, tires, food packages, core samples, fossils, paintings, pathology samples and packages suspected of containing contraband and explosives are examples of objects routinely examined. In addition, cabinet x-ray systems are used in veterinary examinations.

Since cabinet x-ray systems are generally located in occupied areas and operated by personnel with little or no training in radiation safety, persons working or passing near the cabinet x-ray system may be subject to excessive x-radiation exposure as a result of either normal system operation or malfunction. Further, several cabinet x-ray system safety device failures have been reported recently, one of which resulted in serious x-ray exposure to the operators.

The purposes of this standard are to limit x-ray emissions from cabinet x-ray systems to levels sufficiently low to insure that any exposure to persons in the vicinity will be below limits recommended by national standards-setting organizations for nonoccupationally exposed individuals, and to prevent accidental radiation emissions due to unsafe design or system malfunction. The standard is designed to achieve these purposes through appropriate performance requirements for radiation attenuation, safety interlock systems, and warning devices and instructions.

The proposed standard would be applicable to cabinet x-ray systems manufactured or assembled on or after the effective date of the standard. As set forth in § 278.214(d), it would also be applicable to the modification of such a certified cabinet x-ray system by a manufacturer in a manner which affects any aspect of performance for which this standard has an applicable requirement. The manufacturer or assembler who creates a cabinet x-ray system by combining an x-ray system with an enclosure would be deemed the system manufacturer, regardless of who manufactures the separate components, and would be responsible for certification and identification of the system in accordance with §§ 278.201 and 278.202 (21 CFR 278.201 and 278.202). When complete systems are provided by the manufacturer in an unassembled form to the purchaser for final assembly, the manufacturer would be required to identify the system and certify that it will meet the requirements of the standard when installed according to the instructions provided.

It is anticipated that additional requirements which pertain to some cabinet x-ray systems will be imposed upon owners or operators by State agencies or other control groups having authority and responsibility.

The proposed standard was reviewed on three separate occasions by the Technical Electronic Product Radiation Safety Standards Committee, a statutory committee which by law must be consulted prior to the promulgation of electronic product standards established under the act. Informal discussions were held with representatives of cabinet x-ray system manufacturers to determine the state of the art in manufacturing, and to propose added features which would provide improved protection against radiation from cabinet x-ray systems and which would be technically feasible. More than 100 representatives of manufacturers, radiation control and public health agencies, consumer groups and others were invited by mail to submit written comments on the proposed standard. Consideration has been given to currently recognized State regulations, and to the latest available scientific and medical data with respect to electronic product radiation. These reviews and discussions were given full consideration in the development of the standard.

The definition of a cabinet x-ray system describes an x-ray system of which a free standing, enclosed x-ray source is an integral component. It would include all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals and in similar facilities. The definition pertains to an installed x-ray source as opposed to a portable x-ray source which may occasionally or temporarily be used within a shielded room. Other definitions used in performance standards previously developed pursuant to the Radiation Control for Health and Safety Act of 1968 have been used in this proposed standard where appropriate. In addition, certain terms have been defined if the meaning might otherwise be ambiguous.

It is recognized that some x-ray systems are being used for inspection of carry-on baggage which do not meet all of the provisions herein required. Under authority of section 358 of the act the Secretary may issue a variance for such products to authorize their manufacture provided the manufacturer meets the radiation protection criteria for such variance as may be prescribed by the Secretary.

The requirements of § 278.214(c)(1) would limit x-ray emission at a point 5 centimeters from the external surface of a cabinet x-ray system to an exposure of 0.5 milliroentgen in any one hour. This limit is based upon the assumption that the system will be located in an area which is uncontrolled for radiation protection purposes. Furthermore, under the usual conditions of workload and occupancy around these x-ray systems, this limit will result in personnel exposures well below limits for nonoccupationally exposed personnel recommended by the International Commission on Radiological Protection, the National Council on Radiation Protection and Measurements, the Federal Radiation Council and most State governments. The limit in the standard is in agreement with that recommended by the American National Standards Institute for an "exempt protective installation" (ANSI Z54.1-1963). The proposed 0.5 mR in one hour limit would also apply to x-radiation emissions from accessible components of the system, such as high voltage generators and image intensifiers. The proposed limit is consistent with the state of the art in manufacturing technology.

Compliance with the exposure limit would be determined under conditions which produce maximum x-ray emission at the external surface of the cabinet, § 278.214(c)(1)(ii). As part of the reporting requirements of § 278.710 (21 CFR 278.710), manufacturers or assemblers responsible for certification of systems would be required to file reports with the Bureau of Radiological Health which would include information on the instruments used for measurements and their calibration procedures. Adequacy of such measurement techniques would then be evaluated on an individual basis by the Bureau.

Some large cabinet x-ray systems are permanently installed directly on existing floors. The standard would define such a floor as part of the cabinet surface and require that it provide radiation shielding adequate to meet the emission limit. A permanently attached floor would be required for any portable cabinet x-ray system.

Requirements are proposed to limit accessibility to radiation by parts of the body inserted into ports, and to prevent insertion of parts of the body into apertures. The intent of the proposed requirement pertaining to ports is to prevent accidental operator exposure to the very intense primary beam. An exposure limit for accessibility has not been included because insertion of any part of the body into a port is considered to be a nonstandard operating procedure. Apertures, on the other hand, are openings designed for ventilation, wiring, piping and ducts. They differ from ports in that it is not normally necessary to insert any part of the body into an aperture during x-ray generation; therefore, the standard would preclude possibility of such insertion.

Failure of safety interlocks has been a major contributing factor in accidental exposures associated with enclosed x-ray systems. Section 278.214(c)(4) would require two independent safety interlocks on each door, one of which results in a physical disconnection of the energy supply circuit to the high voltage generator when the door is opened. One safety interlock would be required on access panels, since it is anticipated that these will normally be opened or removed only during servicing. Section 278.214(c)(4)(iii) would preclude the use of safety interlocks as control devices by requiring a separate control to resume x-ray generation following functioning of any interlock.

In at least one reported case, a ground fault caused x-ray production to continue when controls were off. The provision of § 278.214(c)(5) is intended to prevent this type of accident.

The provisions of § 278.214(c)(6) for controls and indicators would be applicable to all cabinet x-ray systems, and are intended to enable the operator to control the use of the system, and to know the status of x-ray generation. A key-actuated control would allow the operator to prevent x-ray generation by removing the key. Two independent warning systems to indicate x-ray generation also would be required. Additional indicators showing when x rays are being generated would be required at doors and ports if the indicator on the control panel is not visible from those locations in order to discourage opening the cabinet door or inserting some part of the body through a port during x-ray generation.

Cabinet x-ray systems designed to be entered by personnel present additional radiation safety problems, and would be subject to other requirements under § 278.214(c)(7). A means would be required for preventing and terminating the generation of radiation from within cabinets designed to admit humans. This is necessary because it cannot be assumed that the system operator will make an adequate visual inspection of the interior prior to initiation of x-ray generation. Activation of warning signals inside the cabinet would be required immediately prior to x-ray generation, rather than when the door is closed, since there may be a considerable time delay between the two. Also, initiation of x-ray generation by an individual within the cabinet would not be possible since this could result in excessive exposures to personnel in the cabinet.

Warning labels would be required by § 278.214(c)(8) for cabinet x-ray systems to discourage unauthorized use and to warn those unfamiliar with the equipment that x rays are generated when the system is in operation. Additional warning labels would be required near ports, as it may be possible to reach through a port into regions with relatively high x-ray exposure levels.

The manufacturer would be required by § 278.214(c)(9) to provide the purchaser with technical data and instructions necessary for proper installation, safe use and maintenance necessary to keep the system in compliance with the standard.

Section 278.214(d) addresses modification of a certified system in a manner affecting any aspect of performance covered by the standard. Examples include installation of a different tube head, addition of ports, replacement of leaded windows with nonleaded windows, or conversion of a radiographic to a fluoroscopic system. If such modifications are done by a person in the business of manufacturing, assembling, or modifying cabinet x-ray systems, that person would be required to recertify and reidentify the system.

The Commissioner of Food and Drugs proposes to order that this amendment to Subpart C of Part 278 be applicable to all cabinet x-ray systems manufactured on or after a date that is one year following the date of FEDERAL REGISTER publication of the final order.

Therefore, pursuant to provisions of the Radiation Control for Health and Safety Act of 1968 (Sec. 358, 82 Stat. 1177–1179; 42 U.S.C. 263f) and under authority delegated to him (21 CFR 2.120), the Commissioner proposes to amend Part 278, by adding thereto a new section to read as follows:

§ 278.214 Cabinet x-ray systems.

(a) *Applicability.* The provisions of this section are applicable to cabinet x-ray systems manufactured or assembled on or after (one year after date of publication of final order in the FEDERAL REGISTER). The provisions of this section are not applicable to systems which are designed exclusively for microscopic examination of material (e.g., x-ray diffraction, spectroscopic, and electron microscope equipment) or to systems for intentional exposure of humans to x rays.

(b) *Definitions.* As used in this section the following definitions apply:

(1) "Access panel" means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open, and permits access to the interior of the cabinet.

(2) "Aperture" means any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x radiation.

(3) "Cabinet x-ray system" means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed "cabinet") which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated; provide radiation attenuation; and exclude personnel from its interior during generation of x radiation. It would include all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

(4) "Door" means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet. For the purposes of paragraph (c)(4)(i) of this section, inflexible hardware rigidly affixed to the door shall be considered part of the door.

(5) "Exposure" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.

(6) "External surface" means the outside surface of the cabinet x-ray system, including the high voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.

(7) "Floor" means the underside external surface of the cabinet.

(8) "Ground fault" means an accidental electrical grounding of an electrical conductor.

(9) "Port" means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation, of an object whose dimensions do not permit complete insertion into the cabinet.

(10) "Primary beam" means the x radiation emitted directly from the target and passing through the window of the x-ray tube.

(11) "Safety interlock" means a device which is intended to prevent the generation of x radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.

(12) "X-ray system" means an assemblage of components for the controlled generation of x rays.

(13) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) *Requirements*—(1) *Exposure limit.* (i) Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface.

(ii) Compliance with the exposure limit in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over a cross-sectional area of ten square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface, and with the door(s) and access panel(s) fully closed and fixed at any other position(s) which will allow the generation of x radiation.

(2) *Floors.* A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.

(3) *Ports and apertures.* (i) The insertion of any part of the human body through any port into the primary beam shall not be possible.

(ii) The insertion of any part of the human body through any aperture shall not be possible.

(4) *Safety interlocks.* (i) Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One of these shall be such that door opening results in physical disconnection of the energy supply circuit to the high voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.

(ii) Each access panel shall have at least one safety interlock.

(iii) Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with paragraph (c) (6) (ii) of this section shall be necessary for resumption of x-ray generation.

(iv) Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.

(5) *Ground fault.* A ground fault shall not result in the generation of x rays.

(6) *Controls and indicators for all cabinet x-ray systems.* For all systems to which this section is applicable there shall be provided:

(i) A key-actuated control to insure that x-ray generation is not possible with the key removed.

(ii) A control or controls to initiate and terminate the generation of x rays other than by functioning of a safety interlock or the main power control.

(iii) Two independent means which indicate when, and only when, x rays are being generated, and which are discernable from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall include display of a clearly legible and visible label bearing the statement "X RAY ON".

(iv) Additional means other than milliammeters which indicate when, and only when, x rays are being generated, as needed to insure that at least one indicator includes a visible display from each door, access panel, and port, bearing the statement "X RAY ON."

(7) *Additional controls and indicators for cabinet x-ray systems designed to admit humans.* For cabinet x-ray systems designed to admit humans there shall also be provided:

(i) A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

(ii) No means by which x-ray generation can be initiated from within the cabinet.

(iii) Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause failure of both the audible and visible warning signals.

(iv) A visible warning signal within the cabinet which remains actuated for the duration of x-ray generation.

(v) Signs indicating the meaning of the warning signals provided pursuant to paragraphs (c) (7) (iii) and (c) (7) (iv) of this section and containing instructions for the use of the control provided pursuant to paragraph (c) (7) (i) of this section. These signs shall be legible, accessible to view, and illuminated when the main power control is in the "on" position.

(8) *Warning labels.* (i) There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any control which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:

CAUTION: X RAYS PRODUCED WHEN ENERGIZED

(ii) There shall be permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement:

CAUTION: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED—X-RAY HAZARD

(9) *Instructions.* (i) Manufacturers of cabinet x-ray systems shall provide for purchasers, and to others upon request at a cost not to exceed the cost of preparation and distribution, manuals and instructions which shall include at least the following technical and safety information: Potential, current, and duty cycle ratings of the x-ray generation equipment; adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the system; and a schedule of maintenance necessary to keep the system in compliance with this section.

(ii) Manufacturers of cabinet x-ray systems which are intended to be assembled or installed by the purchaser shall provide instructions for assembly, installation, adjustment and testing of the cabinet x-ray system adequate to assure that the system is in compliance with applicable provisions of this section when assembled, installed, adjusted and tested as directed.

(d) *Modification of a certified system.* The modification of a cabinet x-ray system, previously certified pursuant to § 278.201, by any person engaged in the business of manufacturing, assembling or modifying cabinet x-ray systems shall be construed as manufacturing under the act if the modification affects any aspect of the system's performance for which this section has an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the system in accordance with the provisions of §§ 287.201 and 278.202.

Interested persons may, on or before December 10, 1973, file with the Hearing Clerk, Food and Drug Administration, Room 6–86, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated September 27, 1973.

A. M. SCHMIDT,
Commissioner of Food and Drugs.

[FR Doc.73–21297 Filed 10–9–73;8:45 am]